5. 510(K) SUMMARY OR 510(K) STATEMENT

Ellipse PRECICE® System
510(k) Summary – K 131677
July 2013

1. **Company:** Ellipse Technologies, Incorporated
13900 Alton Parkway, Suite 123
Irvine, CA 92618

Contact: John McIntyre
Vice President, RA/QA/CA
Phone: (949) 837-3600 x203
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OCT 11 2013

2. **Proprietary Trade Name:** Ellipse PRECICE System

3. **Classification Name:** Intramedullary Fixation Rod (21 CFR 888.3020)

4. **Product Code:** HSB (Rod, Fixation, Intramedullary and Accessories)

5. **Product Description:** The Ellipse PRECICE System is composed of the modified PRECICE nail (supplied sterile), locking screws, surgical instruments and an external remote controller (ERC). The nail is available in tibia or femur models with various diameters, lengths and screw hole configurations to accommodate a variety of patient anatomies. The locking screws are also available in a variety of diameters and lengths. The modified PRECICE nail is supplied sterile by gamma radiation while the locking screws and PRECICE specific accessories are supplied non-sterile and must be sterilized prior to use. The nail contains an enclosed rare earth magnet, telescoping lead screw/nut assembly, and planetary gearing.

6. **Indications:** The Ellipse PRECICE System is indicated for limb lengthening of the tibia and femur.

7. **Substantial equivalence:** Documentation that includes mechanical test results and detailed comparison to the predicate devices demonstrates that the Ellipse PRECICE System is substantially equivalent to the following 510(k) cleared device:

- Ellipse Intramedullary Limb Lengthening System (K101997)

Substantial equivalence is based on similar indications for use, designs, and on *in vitro* testing performed.

The modified Ellipse PRECICE Nail and the predicate device have the same intedned use. Specifically, the modified Ellipse PRECICE Nail and the predicate are both designed to lengthen the femur or tibia. These devices are both available in a variety of screw hole patterns and geometrical configurations to accommodate different patient anatomies and implantation methods.

The modified Ellipse PRECICE Nail has similar technological characteristics and principles of operation as that of the predicate. Both the modified PRECICE Nail and the predicate are Titanium intramedullary nails with a telescoping portion that can adjust the length of the implant. Both devices are inserted into the intramedullary canal of the femur or tibia and secured with locking screws. Both devices are adjusted non-invasively by the Ellipse external remote controller (ERC). The overall length of the modified Ellipse PRECICE System is similar to the overall length of the predicate.

The differences between the modified PRECICE System and the predicate device are as follows:

- Addition of tibia-specific models
- Two new screw-hole configurations
- Stroke Lengths of 50 mm and 80 mm
- Start length 195 mm to 365 mm
- Non-modular device
- Addition of 3 new biocompatible materials
- New style package to accommodate the non-modular design

Substantial equivalence is based on similar indications for use, designs, and on *in vitro* testing performed. Testing on the modified PRECICE System included functional testing according to the methods outlined in the standard ASTM F1264-03, O-ring seal performance testing, shelf life testing for the packaging after 6-months of accelerated aging and additional biocompatibility testing. Tests that were performed on the original PRECICE nail which are applicable to the modified device include validation of the gamma radiation sterilization cycle in accordance with the VD_{max}^{25} methodology as given in ISO 11137-2 to verify that the gamma radiation sterilization process provides a sterility assurance level of 10^{-6}, and biocompatibility in accordance with ISO 10993-1 for the intended use of the device. Conclusions can be drawn from these tests that the modified PRECICE System is safe and effective and meets the performance specifications.

The following specific tests have been performed in order to establish equivalence to the predicate devices:

Test Description	Applicable Test Standard
PRECICE, Static Four Point Bend	ASTM F1264
PRECICE, Dynamic Four Point Bend	ASTM F1264
PRECICE, Static Torque to Failure	ASTM F1264
6 Month Shelf Life Packaging Validation	ISO 11607-1
Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose	ANSI/AAMI/ISO 11137-2
Biocompatibility	ISO 10993-1
Device functionality and verification	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 11, 2013

Ellipse Technologies, Incorporated
Mr. John McIntyre
Vice President, Regulatory, Quality, and Clinical Affairs
13900 Alton Parkway, Suite 123
Irvine, California 92618

Re: K131677
Trade/Device Name: Ellipse PRECICE® System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 15, 2013
Received: July 16, 2013

Dear Mr. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131677

Device Name
Ellipse PRECICE® System

Indications for Use *(Describe)*
The Ellipse PRECICE System is indicated for limb lengthening of the tibia and femur.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices